

**POWDER- zinc oxide powder**  
**Oxygen Development LLC**

*Disclaimer: Most OTC drugs are not reviewed and approved by FDA, however they may be marketed if they comply with applicable regulations and policies. FDA has not evaluated whether this product complies.*

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**Hawaiian Tropic mineral translucent powder sunscreen broad spectrum SPF 30**

**Active Ingredient**

Zinc oxide 24.5%

Sunscreen Agent

**Uses**

Helps prevent sunburn

If used as directed with other sun protection measures (see Directions), decreases the risk of cancer and early skin aging caused by the sun

**Warnings**

For external use only.

Do not use on damage or broken skin.

When using this product: Avoid inhalation.

Keep out of eyes. Rinse with water to remove.

Stop use and ask a doctor if rash occurs.

Keep out of reach of children.

if product is swallowed, get medical help or contact a Poison Control Center right away.

**Directions**

Apply liberally 15 minutes before sun exposure

Use a water resistant sunscreen if swimming or sweating. Reapply at least every 2 hours.

Children under 6 months: Ask a doctor

Sun Protection Measures. Spending time in the sun increases your risk of skin cancer and early skin aging. To decrease this risk, regularly use a sunscreen with a Broad Spectrum SPF value of 15 or higher and other sun protection measures including limit time in the sun, especially from 10 a.m - 2 p.m, wear long-sleeved shirts, pants, hats, and sunglasses

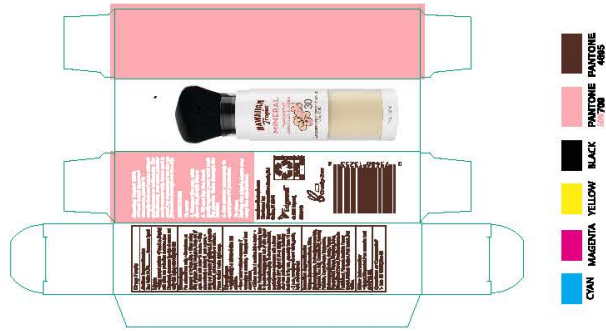
**Inactive Ingredients:**

Calcium Aluminum Borosilicate, Silica, Ethylhexylglycerin, Sodium Dehydroacetate, Fragrance, Sea Salt, Ceramide NP, Ascorbyl Palmitate, Caprylic/Capric Triglyceride, Triethoxycaprylsilane, Carica Papaya (Papaya) Fruit Extract, Mangifera Indica (Mango) Fruit Extract, Passiflora Incarnata Fruit Extract, Plumeria Acutifolia Flower Extract, Psidium Guajava Fruit Extract, Iron Oxides

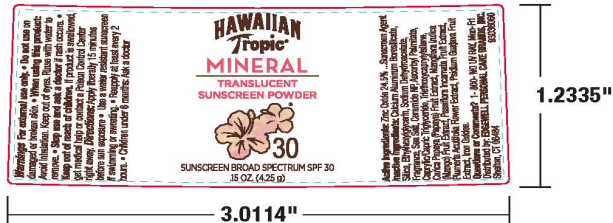
**Other information**

Protect this product from excessive heat and direct sun

**Package**



# TOP OF COMPONENT



white plate

Customer: **Oxygen**  
 Folder: **Oxygen•artwork**  
 File: **93036060 US-SC-HT Mineral Powder Brush \_15 OZ lbl.ai**  
 ITEM#: **TBD** PRECISION#: **TBD**  
 SIZE: **1.2335" x 3.0114" w/.0312" cr • Tapered**  
 JOB#: **TBD**  
 UNWIND: **TBD**  
 SUBSTRATE: **Clear BOPP**  
 DATE: **6/24/2021**

PREPARED BY: **JR**  
 PROOF #: **1**

## Color Guide:

- ☐ dieline does not print
- ☐ deco area does not print
- ☒ white plate
- ☐ PMS 197 C
- ☐ PMS 7499 C
- ☐ PMS 709 C

- ☐ PMS 871 C
- ☐ PMS 4695 C



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**IMPORTANT:** Please review proof for typographical errors, format, style and color breaks. This is a representation of the desired color. Please reference PANTONE® color guide for a more accurate color.

**PLEASE NOTE:** Before proceeding, all proofs and revised proofs **MUST** be signed and returned.

☒ **Approved**
☐ **Not Approved**

## POWDER

zinc oxide powder

### Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:61354-017
Route of Administration	TOPICAL		

**Active Ingredient/Active Moiety**

Ingredient Name	Basis of Strength	Strength
<b>ZINC OXIDE</b> (UNII: SOI2LOH54Z) (ZINC OXIDE - UNII:SOI2LOH54Z)	ZINC OXIDE	24.5 g in 100 g

**Inactive Ingredients**

Ingredient Name	Strength
<b>CALCIUM ALUMINUM BOROSILICATE</b> (UNII: 3JRB8A35M0)	48.26 g in 100 g
<b>SILICON DIOXIDE</b> (UNII: ETJ7Z6XBU4)	25 g in 100 g
<b>ETHYLHEXYLGLYCERIN</b> (UNII: 147D247K3P)	0.5 g in 100 g
<b>SODIUM DEHYDROACETATE</b> (UNII: 8W46YN971G)	0.5 g in 100 g

**Packaging**

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:61354-017-01	1 in 1 CARTON	10/28/2021	
1		100 g in 1 BOTTLE; Type 0: Not a Combination Product		

**Marketing Information**

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part352	10/28/2021	

**Labeler** - Oxygen Development LLC (137098492)**Establishment**

Name	Address	ID/FEI	Business Operations
Oxygen Development LLC		137098492	manufacture(61354-017)

Revised: 10/2021

Oxygen Development LLC